K121284
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510(k) Summary

JUN 14 2013

"510(k) Summary"
As required by section 807.92(c)
For
Chabner XRT™ Garments

June 3, 2013

1. Company Name and Address

   a. Sponsor/Manufacturer

   Bffl Co. Inc.
   20 Kensington Road
   Scarsdale, NY 10583

   b. Consultant/Contact

   Evan P. Phelps
   OFW Law
   600 New Hampshire Ave, Ste. 500
   Washington D.C. 20037
   ephelps@ofwlaw.com
   Tel: (202) 789-1212
   Fax: (202) 234-3550

2. Establishment Registration Number: Not yet assigned

3. Device Name:

   a. Trade Name: Chabner XRT™ Garments
   b. Common/Usual Name: Patient Support and Positioning Garments
   c. Classification Name: Accessory to Medical Charged-Particle Radiation Therapy System

4. Device Classification:

   a. 21 C.F.R. § 892.5050 (Class II)
   b. Product Code: IYE
   c. Classification Panel: Radiology

5. Legally Marketed Predicate Devices:

    a. MR Patient Positioning Devices
        i. 510(k) Owner: Med-Tech, Inc. (d.b.a. CIVCO Medical Solutions)
        ii. 510(k) Number: K111340
        iii. 21 C.F.R. § 892.5050 (Class II)
        iv. Product Code: IYE

    b. Moldcare Head & Neck Cushion
        i. 510(k) Owner: Med-Tec., Inc.
        ii. 510(k) Number: K982624
        iii. 21 C.F.R. § 892.5050 (Class II)
        iv. Product Code: IYE

6. Device Description

The device is a non-sterile garment worn by patients as an aid in the support and positioning of patients during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures.

There are three versions of the garment: 1) brassiere; 2) athletic style shorts; and 3) girdle. All versions of the device are devoid of metal and can be worn for use with all treatment or diagnostic machines without causing a bolus (i.e., the materials do not mimic the properties of tissue during a radiological procedure) or attenuation effect. All materials used in the device's construction are < 1 mm in thickness.

Clear thermoplastic polyurethane (TPU) windows are incorporated into the device to enable clinicians to view index tattoos, the midline, bony landmarks, and other treatment parameters, as created by the light field that is projected by the treatment or diagnostic machine onto the patient's body. The compressive nature of the materials used in the device's construction, along with various adjustment features incorporated into the device, assist the clinician in positioning the body and to reproduce the desired body geometry, treatment position, and patient-to-machine alignment prior to each radiological procedure. Radiation passes through the TPU material without affecting therapy or diagnosis.

Because the device is worn as a garment, they offer the added benefit of protecting the patient's dignity during such procedures that, in turn, increases the patient's overall comfort during the process.

7. Intended Use

Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures.

The Chabner XRT™ Garments are not intended for pediatric use.

8. Technological Characteristics and Substantial Equivalence Evaluation

The Chabner XRT™ Garments are substantially equivalent in terms of intended use, operating principles, and operational specifications to CIVCO's MR Patient Positioning Devices (K111340) and Med-Tec. Inc.'s Moldcare Head and Neck Cushion (K982624) which are both legally marketable patient support and positioning aids classified by the agency as accessories to medical charged-particle radiation therapy systems. Like the CIVCO MR Patient Positioning Devices and Med-Tec. Inc. Moldcare Head and Neck Cushion, the Chabner XRT™ Garments are intended to be used as an aid in the support and positioning of patients during MR, radiological, and other procedures, are radiotranslucent, conform to the individual patient's body shape, and contact the body for less than a 24 hour period of time.

Feature	Chabner XRT™ Garments	MR Patient Positioning Devices K111340 CIVCO	Moldcare Head & Neck Cushion K982624 Med-Tec, Inc.
Indications for Use	Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures. The Chabner XRT™ Garments are not intended for pediatric use.	CIVCO patient Positioning devices are used to aid in the support and positioning of patients during MR, radiological, and other procedures.	The intended use of this device is to provide an additional aid to the fast and accurate repeat positioning of the patient for radiation or other treatment. The device forms to the back of the patient's head and eliminates the usual range of movement of ordinary head cups.
Radiotranslucent	Yes	Yes	Yes
Conforms to patient's body shape	Yes	Yes	Yes

Device Body Contact Category (ISO 10993-1)	Surface devices, intact skin; limited contact duration (<24 hours).	Surface devices, intact skin; limited contact duration (<24 hours).	Surface devices, intact skin; limited contact duration (<24 hours).

There are no significant differences between the Chabner XRT™ Garments and the predicate devices. However, they do differ from the predicate devices in that they are produced as wearable compression garments that have the added benefit of protecting patient dignity; whereas, the predicate devices are not worn on the body. This difference does not affect the device's safety and efficacy.

9. Substantial Equivalence Conclusion

The Chabner XRT™ Garments are substantially equivalent to the CIVCO MR Patient Positioning Devices and Med-Tec. Inc. Moldcare Head and Neck Cushion with respect to intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 14, 2013

BFFL Co., Inc.
% Mr. Evan P. Phelps
Counsel
OFW Law
600 New Hampshire Avenue, NW, Suite 500
WASHINGTON DC 20037

Re: K121284
Trade/Device Name: Chabner XRT Garments
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: May 10, 2013
Received: May 15, 2013

Dear Mr. Phelps:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121284

Device Name: Chabner XRT Garments

Indications for Use:

Chabner XRT™ Garments are intended to be used as an aid in the support of the patient during X-ray, computed tomography, magnetic resonance imaging, radiotherapy, and other diagnostic radiological procedures.

The Chabner XRT™ Garments are not intended for pediatric use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K121284